Department of Health

Three Capital Hill
Providence, RI 02908-5097

TTY: 711
www.health.ri.gov

November 2, 2009

Timothy J. Babineau, MD
Chief Executive Officer
Rhode Island Hospital
593 Eddy Street
Providence RI 02903

Dear Dr. Babineau:

The Department of Health concluded our investigation at Rhode Island Hospital regarding yet another incident involving a patient receiving a surgical procedure in error. The Department's findings and Statement of Deficiencies (SOD) are enclosed. Pursuant to the provisions of the "Rules and Regulations for Licensing of Hospitals", the Hospital is required to file a Plan of Correction with the Department within fifteen (15) days.

Also enclosed is an amendment to the Immediate Compliance Order served on the Hospital on 26 October 2009 and outlining additional conditions I have determined necessary to ensure the ongoing safety for patients scheduled for surgical procedures at Rhode Island Hospital. The conditions of the order are effective forthwith.

Finally, as discussed at our meeting on Wednesday, 28 October 2009, the Hospital's continued failure to effectively implement policies and practices to ameliorate this particular problem is frustrating and significantly damages the public's perception of safety and the credibility of RI Hospital's ability to consistently provide for safe surgical procedures. Subsequently, I believe additional sanctions are needed to highlight the critical nature and importance of this issue. The Hospital is issued a 2nd REPRIMAND and is assessed a fine in the amount of one hundred and fifty thousand dollars ($150,000).

The Hospital is hereby required to submit payment of this fine within thirty (30) days of the receipt of this letter. Address payment to the State of Rhode Island General Treasurer.

If the Hospital is aggrieved by the discipline set forth in this letter, it may request a hearing on these matters within thirty (30) days.

If you have any questions in these matters, please contact me at 222-2231 or Michael S. Varadian, Executive Director, Environmental and Health Services Regulations at 222-4727.

Thank you,

David R. Gifford, M.D., M.P.H.
Director of Health

Encl: (1) Statement of Deficiencies
(2) Amended Immediate Compliance Order

Cc: Lawrence Auburn, RI Hospital Board Chair
George Vecchione, Lifespan CEO
Al Vericchia, Lifespan Board Chair

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

RHODE ISLAND DEPARMENT OF HEALTH
DAVID R. GIFFORD, MD, MPH, in his capacity as
DIRECTOR

IN THE MATTER OF:
RHODE ISLAND HOSPITAL
LICENSE #: 00121
593 EDDY STREET
PROVIDENCE RI 020902

AMENDED IMMEDIATE COMPLIANCE ORDER

Now comes the Director of Health of the State of Rhode Island, and pursuant to Rhode Island General Laws, section 23-17-21 makes the following findings:

1) Rhode Island Hospital (hereinafter the "Hospital") is a hospital located on Eddy Street in the City of Providence, County of Providence, State of Rhode Island, which is licensed as a hospital by the Office of Facilities Regulation within the Department of Health of the State of Rhode Island pursuant to section 23-17-1, et seq. of the General Laws of the State of Rhode Island.

2) Pursuant to regulation and as a condition of its license, the Hospital is required to provide care and services in accordance with written policies and procedures pertaining to invasive procedures. The Hospital is further required to comply with all rules and regulations requiring the provision of care and services to all patients in accordance with the prevailing community standard of care and in a manner that maintains the health and safety of individuals, and to ensure that patients do not undergo unnecessary and/or unwanted procedures.

3) Whereas the Hospital in accordance with an Interim Consent Agreement with the Department dated May, 2009 and signed on 6 June 2009, copy attached and made a part hereof (Exhibit A), developed and implemented a comprehensive training initiative with all surgical staff to:
    i) Increase physician and staff feedback about the policies and procedures to prevent incorrect surgery or surgical site;
    ii) Improve near miss reporting from physicians and staff about the policies and procedures to prevent incorrect surgery or surgical site;
    iii) Ensure staff awareness and competency regarding changes to the policies and procedures; and
    iv) Improve the time out process;

4) Whereas, a review by the Department of Health, initiated on 22 October 2009, indicates that the Hospital failed to:
    (i) Fully implement, by 30 July 2009, the Hospital's plan of correction dated 5 June 2009, copy attached and made a part hereof (Exhibit B), regarding the Hospital's plan to include provisions for policy clarification and staff education based on operating room staff recommendations made during staff feedback sessions held during May 2009 and implementation of the Surgical Executive Committee's recommendation regarding surgical team culture and any subsequent changes in policy.
    (ii) Provide surgery care and services in accordance with written policies and procedures pertaining to time-out procedures and surgical site markings;

5) Pending finalization of the Department's review, the Director issued an Immediate Compliance Order dated 26 October 2009, copy attached and made a part hereof (Exhibit C) requiring the Hospital to ensure every surgery at RI Hospital will be observed by a licensed clinical professional, not assigned to the subject surgery team, trained to observe surgical site marking and time out procedures.

6) The Department completed the review on 28 October 2009. The results of this review as set forth in the statement of deficient practice (hereafter "survey"), a copy of which is attached hereto and made part hereof (Exhibit D), indicates that the Hospital failed to provide surgery care and services in accordance with the Hospital's written policies and procedures pertaining to surgical site markings and time-out procedures.

7) Therefore, based on the foregoing, the Director finds that without intervention of the Department of Health and issuance of this Amended Immediate Compliance Order, the health, safety, and welfare of the patients scheduled for surgical services will be in jeopardy.

The Rhode Island Hospital is herein ordered to:

A) The Hospital is ordered to continue the direct observation of surgical-site marking and time-out procedures for any and all surgeries conducted under the Hospital's license for at least one (1) year and will report to Health quarterly regarding its findings, recommendations for modifications to its policy and procedures, and any variations from Hospital policy and procedures or sooner if it determines immediate changes are warranted. The individuals who are not members of the surgical team shall observe surgical marking and time out procedures for the purpose of compliance and shall point out to the team when the policy is not being followed. The observers are to observe for near misses also and for opportunities to simplify steps in the process.

    1) The observers will also share their findings and recommendations with the Hospital's Board of Trusties and the Joint Commission's Center for Transforming Healthcare.

    2) The Hospital may petition the Department of Health for relief from section A after one year. This petition must be made in writing and it shall include a substantial showing of compliance with the requirement of section A. Relief from the requirement is at the sole discretion of the Department of Health.

B) The Hospital will immediately adopt in policy and practice the Rhode Island Uniform Surgical Safety Checklist and Standard Definition, a copy of which is attached hereto and made part hereof (Exhibit E) and to include;

    1) Mandate that the surgeon marks the surgical site in pre-op area with assistance from a 2nd licensed professional;

    2) Require that the surgeon incorporate the use of primary source verification (i.e., consent, H&P, radiology report if imaging done) prior to incision, and

    3) Develop a comprehensive plan on how the Hospital will continually revise protocols, educate staff, and implement changes based on PSO data, "good-catches", input from clinical consultant(s), and operating room monitors.

C) The Hospital shall, within twenty-one (21) days, schedule a one (1) day shut down of elective surgical procedures to conduct a mandatory training/review the RI uniform surgical safety checklist and standard definition as well as the hospitals site-marking and time-out procedures with all surgical staff, to include at least the following:

   1) Identification of any ambiguities in the policies as they relate to any specific surgical specialties or procedures related to surgical-site markings and time-out procedures.

D) The Hospital shall with-in forty-five (45) days install audio and video monitoring equipment in all operating sites for all surgeries to ensure monitoring and reviews for each surgical physician, to include:

   1) an analysis of and recommendations regarding at least the safety of surgical services, implementation of site-marking and time-out procedures, and team dynamics of the surgical team.
   2) Patient notice and consent documentation about the audio/video recording in accordance with existing protections of personal medical information.
   3) A minimum review of two (2) surgical events per year for each surgical physician.

E) The Hospital is ordered to continue timely implementation of any and all previously ordered or agreed upon conditions and stipulations regarding the implementation of time-out protocols, surgical site markings, and prevention of incorrect surgery or surgical site unless specific relief is requested in writing to the Department of Health.

F) Compile a complete a summary of the Hospital's incidents involving specific surgical errors between 2005 and the present, and forward this summary to the following (with cc to the Department of Health):

   1) The Joint Commission's Center for Transforming Healthcare,
   2) The Centers for Medicare and Medicaid Services
   3) The Rhode Island State Medicaid Office
   4) The Residency Review Training Commission

Not withstanding existing Consent Agreements and previously established reporting requirements and any further actions or sanctions by the Department, this order remains in effect until further notice.

11/3/09

David R. Gifford, MD, MPH — Date
Director, RI Department of Health

EXHIBIT A

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

RHODE ISLAND DEPARMENT OF HEALTH
DAVID R. GIFFORD, MD, MPH, in his capacity as
DIRECTOR

IN THE MATTER OF:
RHODE ISLAND HOSPITAL
LICENSE #: 00121
593 EDDY STREET
PROVIDENCE RI 020902

INTERIM CONSENT AGREEMENT CLARIFICATION

Now comes the Director of Health of the State of Rhode Island, and pursuant to Rhode Island General Laws, section 23-17-21 makes the following findings:

1. Rhode Island Hospital (hereinafter the "Hospital") is a hospital located on Eddy Street in the City of Providence, County of Providence, State of Rhode Island, which is licensed as a hospital by the Office of Facilities Regulation within the Department of Health of the State of Rhode Island pursuant to section 23-17-1, et seq. of the General Laws of the State of Rhode Island.

2. Pursuant to regulation and as a condition of its license, the Hospital is required to provide care and services in accordance with written policies and procedures pertaining to invasive procedures. The Hospital is further required to comply with all rules and regulations requiring the provision of care and services to all patients in accordance with the prevailing community standard of care and in a manner that maintains the health and safety of individuals, and to ensure that patients do not undergo unnecessary and/or unwanted procedures.

3. A preliminary review by the Department of Health, initiated on 12 May 2009, indicates that the Hospital failed to provide surgery care and services in accordance with written policies and procedures pertaining to time out procedures and patient safety.

The Director and the Hospital agree, based on this preliminary review, the Hospital will implement the following immediate actions:

Rhode Island Hospital agrees to:

1. Increase physician and staff feedback about the policies and procedures to prevent incorrect surgery or surgical site by implementing the following:
    a. Urgently institute a series of interdisciplinary meetings for all nurses, surgeons, anesthesiologists and nurse anesthetists involved in operating room procedures to actively solicit input on the strengths, weaknesses and opportunities for improvement in the existing policies and procedures designed to prevent incorrect surgery or surgical site. Surgery will be suspended for each surgical discipline at least two to three hours in order to accommodate these meetings and all meetings will occur within the next two weeks. The discussions at the meetings should specifically include unique situations for which current policies may not be optimum, including, but not limited to multi-site surgeries, midline surgeries that have laterality once the incision is made, and surgeries where site markings are difficult (e.g., oral, vaginal or ocular surgeries).
    b. Provide the Department of Health with a summary report of the findings from these meetings, within 15 days of the conclusion of the aforementioned staff meetings, including changes that

need to be made both to the policies and procedures as well as the culture of physicians, nurses and other staff involved in the operating rooms.

c. A plan within the next 45 days for how surgeons, anesthesiologists and nurses will provide regular and ongoing feedback on the hospital policies and procedures and that addresses how the hospital will improve the team culture about collaboration in carrying out hospital policies and procedures.

2. Improve near miss reporting from physicians and staff about the policies and procedures to prevent incorrect surgery or surgical site by implementing the following:

   a. Complete a letter of agreement with a Rhode Island Department of Health certified Patient Safety Organization within the next 30 days, and contract within the next 60 days, to initiate a near miss reporting program about the hospital's policies and procedures for preventing incorrect surgery or surgical site.

   b. Immediately submit reports twice monthly to the Department of Health on the number of near miss reports collected, regarding any hospital procedure that could ultimately have impacted on verification/identification for correct patient, correct surgical procedure, and correct site/side.

   c. Develop a plan within 30 days to address near miss reports, and if appropriate, revise the applicable policies and procedures.

   d. Produce monthly reports on any changes to relevant policies and procedures from either near miss reporting or physician and staff feedback within 30 days after the plan is implemented.

3. Following the implementation of Step 1 above, ensure staff awareness and competency regarding changes to the policies and procedures by implementing the following:

   a. A plan within the next 30 days for how surgeons, anesthesiologists and nurses will work together to develop, implement and stay current with the policies and procedures.
   b. A plan for continual education of physician, nursing and other operating room staff regarding applicable new or changing policies.
   c. An updated plan for ongoing competency assessment regarding policies and procedures.

4. Improve the time out process by implementing the following.

   a. Add either a preoperative history & physical for elective surgeries, or a pre-op note for inpatient surgeries, to the time out checklist to be reviewed and used for verification of site(s).
   b. Provide a script for physicians to use regarding visualization of surgical site marking(s) and/or descriptive location when no site marking is possible during the time out.
   c. Develop a collaborative working group including physicians and nurses to review surgery specific site marking to assure visibility of marking after patient draping.

Not withstanding any further actions or sanctions by the Department, this order remains in effect until further notice.

Entered this 18th day of May, 2009.

6/5/09
David R. Gifford, MD, MPH Date
Director, RI Department of Health

6/5/09
Timothy J. Babineau, MD, Date
President & CEO, Rhode Island Hospital

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	121	A. BUILDING _____ B. WING _____	C 05/15/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	593 EDDY STREET PROVIDENCE, RI 02902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 0	INITIAL COMMENTS A complaint investigation survey was conducted at this facility State deficiencies were identified.	Z 0		
Z 160	ORGANIZATION & MANAGEMENT 12.2 Organization 12 2 Each hospital department and service shall maintain: a) clearly written definitions of its organization, authority, responsibility and relationships; b) written patient care policies and procedures; and c) written provision for systematic evaluation of programs and services. This Requirement is not met as evidenced by: Based on record review, staff interview, and review of hospital policies and procedures, it was determined that the hospital failed to ensure compliance with the hospital policy and procedure entitled, "Universal Protocol Verification of the Patient's Identity, Surgical Procedure, and Surgical Site", for 2 of 8 relevant sample patients (Patient ID #1 and ID #3) Findings are as follows: Review of the policy, "Universal Protocol Verification of the Patient's Identity, Surgical Procedure and Surgical Site", states, Under Section III, Procedure, Item #3d) includes, under Exceptions to Site Marking: "Surgery conducted through body orifice". Under Item #6, Time Out, c) states: "Active participation is required confirming that the site and side marking is visible prior to initiating the procedure Team members will verbally acknowledge that the mark is visible after	Z 160	The plan to ensure compliance with the hospital policy entitled, "Universal Protocol Verification of the Patient's Identity, Surgical Procedure and Surgical Site" includes holding a series of multidisciplinary meetings with surgeons, anesthesiologists and nurse anesthetists and perioperative staff to solicit input on the strengths, weaknesses and opportunities for improvement in the existing policy. Specific information will be requested on situations such as multi-site surgeries and surgeries where site markings are more difficult or not required at present. In addition, the hospital has initiated an on-line survey to garner feedback from those who may prefer a more private and anonymous form of providing information. A report that encompasses the findings of the meetings and the survey will be submitted to the RI DOH.	5/29/09 6/5/09 6/15/09

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Z 160	Continued From page 1 prepping and draping " 1 Patient ID #1 was scheduled for elective surgery for right alveolar bone graft from the right hip. to the right soft palate, on 5/11/09. The right hip was marked appropriately in the Holding area by the Preoperative Nurse. The patient entered the Operating Suite, and patient identification was performed per hospital policy, with verification of patient identity and the scheduled surgical procedure, including the site and side. The Surgeon did complete the marking of the surgical site by placing initials on the line drawn by the Preoperative Nurse on the right hip. The prepping and draping of the patient was completed On 5/12/09 between 11:00 AM and 2:00 PM, the Surgical Team, including the Surgeon, was interviewed All indicated that the Surgeon did not ask for verification of the visibility of the site marking during the Time Out performed, however, no one in the room during the surgery voiced the breach of hospital policy. In addition, the Surgeon proceeded to make a mark on the left side (incorrect side) of the patient's face, close to the ear, without making the team aware This is also not in accordance with hospital policy for surgery within orifices The surgeon then proceeded to cover this mark with a surgical drape After the start of the surgery, the Surgical Resident looked over the Surgeon's shoulder, and questioned the Surgeon regarding what side of the mouth was being worked on It was noted that the Surgeon had started to operate on the left palate, rather than the intended right palate. Further interview with the Surgeon indicated that the left face was marked because the Surgeon	Z 160	Once the input findings have been summarized, the Surgical Executive Committee (SEC) will discuss what changes need to be made in the policy and procedure. The SEC will also address improvements that could be made in the team culture to encourage collaboration in carrying out the policy, including supporting staff to speak up if they have concerns that the policy is not being followed Clarifications to the policy will be made and staff will be educated as to any changes. To ensure a more consistent practice during the time out process, a script will be developed for the team to use regarding visualization of the site marking. Monitoring of compliance with the script will be done by direct observation of a sample of cases in each OR beginning 8/30/09 and continuing for 3 months with further monitoring depending on the results of the first 3 months. 6/5/09 MV	7/30/09 7/30/09

RI Department of Health

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Z 160	Continued From page 2 "thought" that the left palate was the correct site. The left palate surgery had already been performed by this Surgeon in November of 2008. The Surgeon felt the need to mark the surgical site because, "No one can see what is being done in the patient's mouth." The surgeon also stated he had felt the procedure was being rushed. Feeling rushed during procedures was a complaint voiced by other staff members as well. Additionally, when the Surgeon was asked how updates to the Universal Protocol are relayed, the response was that these are typically received from the nurses. There was no evidence that the Surgeon had reviewed the updated policy, and/or had relayed concerns or feedback in regards to his specialty 2. Patient ID #3 had scheduled surgery for a left leg irrigation and debridement on 5/15/09. During surveyor observation of the Time Out process at 8 15 AM in the Hasbro unit operating room, the left leg marking was visible after the prepping and draping It was noted, however that the Surgeon did not verify with the team that the site mark was visible during this Time Out, but instead stated, at the completion of the Time Out, "Is everyone in agreement?" This is not in accordance with the hospital policy to verify visualization of the site marking during the Time Out	Z 160		
Z 185	ORGANIZATION & MANAGEMENT 13 3 Personnel 13 3 Provisions shall be made for orientation and ongoing education programs for all personnel There shall be written evidence that staff demonstrate competencies necessary to work in specific areas and/or with specific patient populations.	Z 185		

RI Department of Health

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Z 185	Continued From page 3 This Requirement is not met as evidenced by: Based on staff interviews, it was determined that the hospital failed to make provisions for ongoing education for all personnel, that includes written evidence that staff demonstrate competencies necessary to work in specific areas and/or with specific patient populations, related to the Universal Protocol Findings are as follows: During interviews with the surgical staff on 5/12/09 and 5/13/09, it was revealed that there are different interpretations of the Universal Policy related to verification of the visualization of the site marking during the Time Out process, after the patient is prepped and draped. In addition, the surgeon indicated that updates to the policy are typically received from the nurses, rather than through hospital initiated methods (i.e., formal training, memos, etc.). Although the surgical staff receives orientation to the policy, and must demonstrate competencies at that time as part of their core competencies, there was no evidence of demonstrated competencies for surgical staff when policy changes/revisions are made. Staff were inconsistent relating how policy changes/revisions are communicated to them. For example, during conversations with Circulating Nurses, the Scrub Nurse, Anesthesiologist, CRNA (Certified Registered Nurse Anesthetists), and Assistant Clinical Manager, and other surgery staff members (on 5/12/09, 5/13/09, and subsequent discussions), all provided varied information as to how policy and procedure changes are communicated (i.e., newsletter, e-mail, inservice, morning meeting, or staff meeting). Several indicated it was often unclear as to which version	Z 185	The SEC will develop a plan for how surgeons, anesthetists and perioperative staff will stay current with policies and procedures. The plan will include expanding the use of the Hospital's on-line learning system, Net Learning, to Medical and allied health staff and residents. Employees already have access to and use NetLearning for on-going education. NetLearning can be used to track participant learning. 8/30/09 When significant changes are made to the UP policy, perioperative staff, physicians, anesthesiologists and nurse anesthetists will be required to demonstrate competence in the policy. Documentation of competency will be placed in the personnel or credentials file. Ongoing Monitoring for continued competency will be done by direct observation of a sample of cases in each OR for 3 months with further monitoring depending on the results of the first 3 months. 6/5/09 mv	

RI Department of Health

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Z 185	Continued From page 4 of the policy is in effect or most current. Many staff felt when concerns are voiced, and/or following surveys conducted by the hospital, they receive little or no feedback The hospital failed to provide evidence that all staff are aware of policy/procedure changes and that they are deemed competent related to the policy change/revision.	Z 185		
Z 370	PATIENT CARE SERVICES 19.6 Patient Care Management 19 6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care. This Requirement is not met as evidenced by: Based on record review and staff interview, it was determined that the hospital failed to provide care and services to all patients in accordance with the prevailing community standard of care for 1 of 8 relevant sampled patients (ID #1). Findings are as follows: The AORN (Association of periOperative Registered Nurses), August 2008 issue, Vol 4, No 8, regarding "Improving Universal Protocol" and "The New Patient Safety Goal Requirements for 2009" reveals, under "Preprocedure Verification Process", that checklists including assessments must be used to review and verify that relevant documentation is available, and is accurately matched to the patient. Patient ID #1 was seen in the Holding area by the Preoperative Nurse prior to a surgical procedure. The nurse completed the Holding Unit assessment, documenting under the verification	Z 370	The nurse who inaccurately documented the side of the marking has been counseled. A sample of his records are being audited for accuracy and completeness, with results of 100% to date. Auditing of his records will continue for another month, unless results fall below 100%, in which case records will be continued to be monitored until compliance is maintained at 100% for a month. Re-education for PACU staff regarding completeness of Holing Unit Assessment Form was done. Staff meeting on more specific information related to correct documentation on form was held. The surgical services department also conducts random audits of 70 pre-op records per month for completeness of consent, and documentation of the procedure in the H&P. Live audits of 50 cases per month are performed on verifications in the OR checklist. These audits are ongoing. 6/5/09	5/15/09 7/5/09 5/20/09 6/3/09 Ongoing

RI Department of Health

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Z 370	Continued From page 5 of the surgical procedure site/side, "Right hip bone graft" However, under nursing notes on the same form, the nurse inaccurately documented, "Mark on left hip area". During an interview on 5/13/09 at 9:05 AM with the Preoperative Nurse, it was acknowledged that the correct right hip was marked in the Holding area, but that a documentation error was made when the "mark on left hip area" was written under the nursing note section of the Holding Unit Assessment, therefore, documentation was not accurately matched to the patient.	Z 370		

Exhibit C

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

RHODE ISLAND DEPARMENT OF HEALTH
DAVID R. GIFFORD, MD, MPH, in his capacity as
DIRECTOR

IN THE MATTER OF:
RHODE ISLAND HOSPITAL
LICENSE #: 00121
593 EDDY STREET
PROVIDENCE RI 020902

IMMEDIATE COMPLIANCE ORDER

Now comes the Director of Health of the State of Rhode Island, and pursuant to Rhode Island General Laws, section 23-17-21 makes the following findings:

1) Rhode Island Hospital (hereinafter the "Hospital") is a hospital located on Eddy Street in the City of Providence, County of Providence, State of Rhode Island, which is licensed as a hospital by the Office of Facilities Regulation within the Department of Health of the State of Rhode Island pursuant to section 23-17-1, et seq. of the General Laws of the State of Rhode Island.

2) Pursuant to regulation and as a condition of its license, the Hospital is required to provide care and services in accordance with written policies and procedures pertaining to invasive procedures. The Hospital is further required to comply with all rules and regulations requiring the provision of care and services to all patients in accordance with the prevailing community standard of care and in a manner that maintains the health and safety of individuals, and to ensure that patients do not undergo unnecessary and/or unwanted procedures.

3) Whereas the Hospital in accordance with a Consent Agreement with the Department dated May 19, 2009 developed and implemented a comprehensive training initiative with all surgical staff to:

   a) Increase physician and staff feedback about the policies and procedures to prevent incorrect surgery or surgical site;
   b) Improve near miss reporting from physicians and staff about the policies and procedures to prevent incorrect surgery or surgical site;
   c) Ensure staff awareness and competency regarding changes to the policies and procedures; and
   d) Improve the time out process;

   A preliminary review by the Department of Health, initiated on 22 October 2009, indicates that the Hospital failed to provide surgery care and services in accordance with written policies and procedures pertaining to time out procedures and surgical site markings.

4. Therefore, based on the foregoing, the Director finds that without intervention of the Department of Health and issuance of this Immediate Compliance Order, the health, safety, and welfare of the patients scheduled for surgical services may be in jeopardy.

The Rhode Island Hospital is herein ordered to:

1. Starting Monday, October 26, 2009, every surgery at RI Hospital will be observed by a licensed clinical professional, not assigned to the subject surgery team, trained to observe surgical site marking and time out procedures.

Not withstanding existing Consent Agreements and any further actions or sanctions by the Department, this order remains in effect until further notice.

10/26/09

David R. Gifford, MD, MPH — Date
Director, RI Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	121	A. BUILDING _____ B. WING _____	C 10/28/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
RHODE ISLAND HOSPITAL	**593 EDDY STREET PROVIDENCE, RI 02902**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
Z 0	INITIAL COMMENTS An "Other" State licensure survey was conducted at this facility. State deficiencies were cited.	Z 0		
Z 160	ORGANIZATION & MANAGEMENT 12.2 Organization 12.2 Each hospital department and service shall maintain: a) clearly written definitions of its organization, authority, responsibility and relationships; b) written patient care policies and procedures; and c) written provision for systematic evaluation of programs and services. This Requirement is not met as evidenced by: Based on record review, staff interview, and review of hospital policies, it was determined that the hospital failed to ensure compliance with the hospital policy entitled, "Universal Protocol Verification of the Patient's Identity, Surgical Procedure and Surgical Site", for patient (ID #1). Findings are as follows: Review of the policy, "Universal Protocol Verification of the Patient's Identity, Surgical Procedure and Surgical Site", states: Under Section III, Procedure, Item #2, Arrival to Preoperative Area, c) states: "In cases where laterality is involved (extremities, head, organs for which there is duplication), the Preoperative RN will use an approved indelible marker to mark the surgical site with a straight line in the Preoperative holding area. This includes procedures involving right/left distinction, multiple structures (such as fingers and toes), or	Z 160		

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	121	A. BUILDING _____ B. WING _____	C 10/28/2009

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Z 160	Continued From page 1 multiple levels (as in spinal procedures; cervical, thoracic lumbar) and bilateral procedures....". Under Item #5, In Operating Room, e) states: "If the line drawn by the Preoperative RN is not where the intended incision will be, the surgeon's initials will be the official confirmation of the surgical site." Under Item #6, Time Out, g) states: "If two procedures are being done on the same patient, the time out must be done before the first procedure, then before you start the second procedure unless both procedures are done through the same approach/incision and by the same surgeon". 1) Patient ID #1 was scheduled for elective outpatient surgery for right middle trigger finger release and right small finger distal interphalangeal (DIP) fusion on 10/22/09. Although the patient's surgery was to include the right middle and right small fingers, the Preoperative Nurse marked a straight line down the patient's right forearm to the wrist, and documented "marked right hand" under nursing notes on the Holding Unit Assessment. The patient entered the Operating Suite, and patient identification was performed per hospital policy, with verification of patient identity and the scheduled surgical procedure, including the site and side. During interviews on 10/23/09 between approximately 10:00 AM and 10:45 AM, with both the Circulating Nurse and the Anesthesiologist that had participated in the identification process in the OR with this patient,	Z 160		

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Z 160	Continued From page 2 both indicated that the Surgeon did verify the correct surgical procedures, including the site and side. Although the surgical marking made by the Preoperative Nurse was not where the intended incision would be, the Surgeon did not initial the intended multiple digits to confirm the surgical sites, and indicate where the intended incisions would be, per hospital policy, which states, "If the line drawn by the Preoperative RN is not where the intended incision will be, the surgeon's initials will be the official confirmation of the surgical site." Instead, the Surgeon completed the marking of the surgical site by placing his initials on the (incorrect) line drawn by the Preoperative Nurse on the patient's forearm. Immediately before the start of the first procedure, the Surgeon called for a "Time Out" with the entire Surgical Team. This included confirmation of the correct side/site, and correct procedures. The procedures were reportedly verified with the surgical consent. During interviews with the entire Surgical Team, including the Surgeon, on 10/23/09 between 8:45 AM and 12:30 PM, there were discrepancies noted regarding the side/site and procedure confirmation by the Surgeon during the Time Out. Both the Circulating Nurse and the CRNA (Certified Registered Nurse Anesthetist) indicated that they heard the Surgeon call the correct sides/sites, and procedures during the Time Out. The Scrub Technician stated she could not remember what was said during the Time Out. The Surgical Fellow assisting the Surgeon indicated that he heard the Surgeon say, "right middle trigger finger release and DIP fusion". The Surgeon indicated that he was focused on the middle finger and said "right middle trigger	Z 160		

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Z 160	Continued From page 3 finger release and DIP fusion". The right middle finger trigger release surgery was completed in the palm area of the right hand. The patient's hand was then turned with the palm down, and the Surgeon and the Surgical Fellow proceeded to perform the DIP fusion on the patient's distal middle right finger, instead of the small finger per the Surgical Consent signed by the patient, the History and Physical, the surgical booking, etc. Additionally, there was no evidence that a Time Out was called by the Surgeon prior to the second incision/procedure, in accordance with hospital policy, which states, "If two procedures are being done on the same patient, the time out must be done before the first procedure, then before you start the second procedure unless both procedures are done through the same approach/incision and by the same surgeon". At the completion of the second procedure, the Surgical Fellow wrapped the hand in a gauze dressing, and the CRNA questioned why the surgery to the small finger had not been initiated. The Surgeon was notified, and after speaking with the patient's contact, proceeded to complete the fusion of the right small finger as had been planned. Again, there was no Time Out, or other acknowledgment by the Surgeon, before the incision on the small finger. During the interview with the Preoperative Nurse, she indicated that she did not mark the patient's digits for the surgery because she did not know where the incision would be made. She indicated that she marks "within" the surgical site, so that she will not be "reprimanded" by the Surgeon. She also indicated that she always marks "for side".	Z 160		

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Z 160	Continued From page 4 During the interview with the Surgeon, he indicated that after the last wrong side surgery at the hospital, a meeting was held at the ASC (Ambulatory Surgery Center) that had resulted in a discussion with the Surgeons and Nurses, related to the potential for problems with multiple surgeries on digits not marked in advance of the surgery by the nurse. He indicated that there was more concern with the side being marked, and the policy was not addressed at that time. He also indicated that the nurses had indicated that they did not always know where the mark should be placed on the digits for the proposed surgery. Although nurse interview revealed that there was concern that they would be reprimanded by the surgeons for marking within the surgical site, he denied that he would dispute such (accurate) markings of the digits by the Preoperative Nurse. 2) Although the Scrub Technician was aware of the correct procedures to be performed, in accordance with the surgical schedule, she handed the Surgical Fellow instruments, including a screw on a screwdriver, for the middle finger fusion, and did not question the Surgeon or the Surgical Fellow regarding the middle finger fusion. 3) During interview with the Surgical Fellow, he indicated that he had not met the patient in the Holding Area, nor had he had a discussion with the patient prior to surgery, because of the time factor in that this patient was the first case. Also, he had not reviewed the patient's Consent Form, or the History and Physical prior to the surgery, as he normally does. He stated he was aware of the planned surgery per an electronic mailing he had received prior to the surgery, and the Surgeon had updated him on the case at the	Z 160		

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Z 160	Continued From page 5 scrub sink. 4) There continues to be discrepancy between inpatient and outpatient surgeries. During an interview on 10/23/09, at approximately 1:45 PM, with the Director of PeriOperative Services, she indicated that Outpatient Surgery had not been marking digits per hospital policy. She also indicated that there seems to be misinterpretation of the Time Out policy regarding multiple incisions. 5) In July 2009, all of RI's 13 acute care hospitals reportedly agreed to a statewide, single, safe surgical protocol in order to improve patient safety. This protocol outlines steps within three phases of surgery; before induction of anesthesia, before incision, and before patient leaves operating room. Although the hospital participated in the announcement of this protocol, and other hospitals have implemented the protocol, Rhode Island Hospital failed to implement all steps in all phases of the protocol.	Z 160		
Z 370	PATIENT CARE SERVICES 19.6 Patient Care Management 19.6 The hospital shall provide care and services to all patients in accordance with the prevailing community standard of care. This Requirement is not met as evidenced by: Based on record review and staff interview, it is determined that the hospital failed to provide care and services to all patients in accordance with the prevailing community standard of care for patient ID #1 related to surgical services.	Z 370		

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Z 370	Continued From page 6 Findings are as follows:: Refer to Z 160 findings, items 1 - 3.	Z 370		

Exhibit E

RHODE ISLAND SURGICAL SAFETY CHECKLIST

All team members have an obligation to verbalize their concerns at any step in the process

Before induction of anesthesia → Before skin incision → Before patient leaves operating room

Briefing Process

- ❑ Completion of site marking by surgeon* and second licensed provider
- ❑ Identification of team members and roles
  - ➢ Each introduce themselves*
- ❑ Surgeon identifies patient, procedure, site/side, (confirmed with consent by RN) and discusses the plan for surgery*
- ❑ Antibiotic status/glycemic control/ beta-blockers/medications needed on field/irrigation as applicable*
- ❑ Patient position*
- ❑ Equipment/implants required for procedure
- ❑ Patient safety considerations: blood, DVT prophylaxis, allergies, special considerations (hearing deficit, language barrier, friable skin, risk for pressure ulcer, Pacemaker, etc.)
- ❑ Relevant information available: X-rays, PACS up on screen, lab work, consent
- ❑ Are we ready to begin induction?

Time-Out Process

- ❑ Initiated by attending surgeon
- ❑ Patient, procedure, site/side identification (confirmed with consent by RN/licensed provider)
- ❑ Surgeon's initials on procedure site/side visible after prepping and draping
- ❑ Can we see the marking?

Debriefing Process

- ❑ Initiated by attending surgeon prior to leaving the operating room
- ❑ Specimen labeling and designation
- ❑ Post-op plan of care (ICU bed, ventilator, etc.)
- ❑ Patient temperature
- ❑ Review of what worked well and what could have been done differently
- ❑ Identify any instrument/equipment concerns
- ❑ Identify edits for physician preference card

Developed with assistance from the World Health Organization

* Joint Commission element of performance

Attachment A

STANDARDIZED DEFINITIONS FOR RHODE ISLAND UNIFORM SURGICAL PROTOCOL

Anesthesia Provider:
A certified and credentialed registered nurse anesthetist (CRNA) or anesthesiologist who will actively participate in the time-out. Includes student and gradate registered nurse anesthetists.

Briefing:
Active communication guided by the appropriate safety checklist to identify team members and confirm patient verification, site and procedure before induction of anesthesia.

Debriefing:
Active communication guided by the appropriate safety checklist to confirm post-operative plan of care before patient leaves the operating room.

Invasive Procedure:
Any procedure involving puncture/incision of skin or insertion of an instrument or foreign material into the body, Excluded are IV and foley catheters.

Licensed Professional:
A licensed health care provider who is involved in the procedure.

Pause:
During the time-out, other activities are suspended, to the extent possible, without compromising patient safety.

Proceduralist:
A licensed professional who is credentialed by the hospital to perform scheduled procedure who will initiate the time-out.

Physician's Assistant:
A physician's assistant (PA) as defined by the Rules & Regulations for licensure by the State that will be assisting with the procedure.

Physician Designee:
Physician, nurse practitioner, or physician's assistant as designated by the attending physician.

Pre-Procedure Area:
Pre-operative area/pre-procedure area - located outside the operating room/procedural area where patient will be admitted and prepared for surgery/procedure.

Immediate pre-procedure area - location within the operating room/procedural area where patient will await entrance to the operating room/procedural suite.

Pre-Procedure Registered Nurse:
The registered nurse who is designated as the individual responsible for preparing the patient for surgery or invasive procedure.

Procedural Registered Nurse/Circulator:
The registered nurse who is responsible for admitting and caring for the patient in the operating room/procedural area throughout the procedure, including the time-out.

Time-Out:

Active communication guided by the appropriate safety checklist involving the entire procedural team, conducted in the location where the procedure will be done immediately prior to starting the procedure.

Multiple Procedures:
A time-out is required for each procedure if the surgical team changes and/or there is a change in patient position.

Scrub Nurse/Technician:
Registered nurse or operating room technician in the scrub role during the surgical/invasive procedure who will actively participate in the time-out.

Stop the Line:
Any member involved in the procedure can ask for clarification or stop the procedure.

Unambiguous marking of surgical site:
Site mark must be clearly marked on or as close as possible to the surgical site by the surgeon/proceduralist with initials. If site is unable to be marked, a mechanism is established to verify patient, procedure, and operative site.

Developed by the Hospital Association of Rhode Island Surgical Protocol Workgroup